Opening Statement of Chairman Walden
Subcommittee on Health
"Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA"
March 14, 2018

(As prepared for delivery)

Good morning, everyone, and thank you for joining us for yet another "UFA" hearing! We have a history of producing bipartisan user fee reauthorizations, most recently as last year, and I look forward to continuing those efforts today.

Whether it be livestock or house pets, the owners of these animals rely on the Food and Drug Administration (FDA) to ensure the availability of safe and effective medical products to keep their animals healthy. Through the Center for Veterinary Medicine, FDA evaluates new drugs to determine the safety and efficacy of those treatments for their stated use. In the case of livestock, CVM must also ensure that the drug will not impact the food supply and not harm the environment or the health of the livestock producer who administers it.

But the hard work of developing and manufacturing these drugs is done by the animal drug industry. And these companies face unique challenges that need to be considered—including an R&D process that involves developing and manufacturing drugs for different species of animals with different physiologies.

Given the success of the human drug user fee programs in expediting approval of treatments by bolstering resources for the agency, the FDA and the animal drug industry came together to propose the animal drug user fee programs. These programs have succeeded in dramatically reducing review times by providing FDA with much needed additional resources. It's a win-win scenario where everyone benefits—including farmers, pet owners, and veterinarians.

Today we are considering the reauthorization of those programs—the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act—both of which expire at the end of this fiscal year. It is critically important that these programs are passed and signed into law well before the end of September.

Before each reauthorization, as set forward in statute, FDA meets with the animal drug industry to reevaluate specific goals for review timelines and solicits comments from stakeholders and members of the public to consider additional

enhancements. Then the final agreement is delivered to Congress for the program to be reauthorized.

For this cycle, that process began in May of 2016. After numerous public meetings, the final negotiated recommendations were sent to Congress in January of this year. This year's agreements include increased collections from industry as well as more aggressive performance goals for FDA. They also include several process improvements and other enhancements. We look forward to hearing more about these agreements from today's witnesses.

Encouraging innovation is a top priority of this committee, and we want to take this opportunity to examine the animal drug approval process to ensure the incentives are in place to encourage innovative treatments to be developed and for generic animal drugs to be made available.

We don't often think of the FDA when it comes to animal drugs, but these programs are critically important to the pet owners of America and our farmers that we rely on to produce the food that feeds our country.

This is important must-pass legislation and we are committed to getting it done on time before these user fee programs expire in September. I'd like to thank our witnesses for being here with us today, and Mr. Mullin for leading this legislative effort for our committee.